

**GAGE**

Occupational and Environmental Health Unit

June 13, 2005

Dr. R. Heslegrave  
Chair, Research Ethics Board

Toronto, Ontario M5B 1W8

Department of Medicine  
University of TorontoDepartment of  
Public Health SciencesDepartment of Occupational  
and Environmental Health  
St. Michael's Hospital

Dear Dr. Heslegrave,

RE: Application for ethical review.

Enclosed please find an application for ethics approval of a study entitled "Cardiovascular Toxicity of Concentrated Ambient Fine, Ultrafine and Coarse Particles in Controlled Human Exposures". This study is funded by the U.S. Environmental Protection Agency - National Center for Environmental Research.

This study will examine the size fractions, components and sources of air pollution responsible for cardiovascular physiologic responses. A new state-of-the-art ambient PM exposure facility (to be built at the University of Toronto in collaboration with Harvard School of Public Health) will allow us to examine responses to fine, ultrafine and coarse CAPs in healthy volunteers.

The study will be carried out using our controlled human exposure facility located at the Gage Occupational and Environmental Health Unit at the University of Toronto. As principal investigator, this study will be under my supervision.

Thank you for your attention to this matter and please do not hesitate to call if you require any additional information.

Sincerely,

  
Frances Silverman, PhD  
Gage Occupational and Environmental Health Unit  
St. Michael's Hospital/University of Toronto  
223 College St.

Toronto, Ontario

M5T 1S9

223 College St.  
Toronto, Ontario  
M5T 1R4Phone: (416) 978-5883  
Fax: (416) 978-260830 Bond St.,  
Toronto, Ontario  
M5B 1W8Phone: (416) 864-5074  
Fax: (416) 304-1902

Enclosures

Application  
TAHSC Appendix  
Budget  
Reviewer's Comments/ Responses to  
Related Study Forms  
Consent Form  
Protocol/Proposal

TAHSC Harmonized Core Application  
Version 15 October 03

## Toronto Academic Health Sciences Committee (TAHSC) HUMAN SUBJECTS RESEARCH APPLICATION

All sections of this application **MUST** be completed before it will be considered for REB review. If not applicable, please indicate "N/A". Unless indicated, **DO NOT** refer to or attach other documents in response to the Research Ethics Board Application questions.

Application submitted to (check all that apply):		*Ethics Review and Approval Status (check all that apply and indicate date where applicable):			
		Application To Be Submitted	Applied, Review Pending	Reviewed	Approved
<input type="checkbox"/>	Baycrest Centre for Geriatric Care	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	Bloorview MacMillan Children's Centre	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	Centre for Addiction and Mental Health	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	Hospital for Sick Children	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	Mount Sinai Hospital	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	St. Michael's Hospital	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	Sunnybrook and Women's College Health Sciences Centre	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	Toronto Rehabilitation Institute	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	University Health Network	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	Other (Specify )	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

\*Please include all relevant correspondence related to ethical review (i.e. REB review letter, replies, approval form).

### **SECTION I: GENERAL INFORMATION**

1. **FULL STUDY TITLE:** Cardiovascular Toxicity of Concentrated Ambient Fine, Ultrafine and Coarse Particles in Controlled Human Exposures
2. **SPONSOR PROTOCOL NUMBER** (if applicable): G4H10792 – Project 3
3. **STUDY PERIOD:**

Expected Start Date: July 2005 Total Study Duration: 5 years

TAHSC Harmonized Core Application  
Version 15 October 03

#### 4. INVESTIGATORS:

##### A. PRINCIPAL INVESTIGATOR

Name: Frances S. Silverman			
Telephone: (416) 978-5883	Pager: N/A	FAX: (416) 978-2608	Email: frances.silverman@utoronto.ca
Dept/Division: Medicine		Program: Gage Occupational and Environmental Health	
Mailing Address: 223 College St., Toronto, ON. M5T 1R4			


**PRINCIPAL INVESTIGATOR AGREEMENT** - I assume full responsibility for the scientific and ethical conduct of the study as described in the this REB application and submitted protocol and agree to conduct this study in compliance with the Tri-Council Policy Statement: Ethical Conduct for Research Involving Human Subjects and any other relevant regulations or guidelines. I certify that all researchers and other personnel involved in this project at this institution are appropriately qualified and experienced or will undergo appropriate training to fulfill their role in this project.



Signature of Principal Investigator

June 13, 2005  
Date

##### B. CO-INVESTIGATOR(S):

Name	Dept/Div/Program	Signature (if required at this institution—see instructions)
Jeffrey Brook	Environment Canada	
Paul Corey	Public Health Sciences, University of Toronto	
James Scott	Gage Occupational and Environmental Health, University of Toronto	
Rob Brook	University of Michigan Health Center	
Julie Kovach	University of Michigan Health Center	
Diane Gold	Harvard School of Public Health	

##### C. STUDY COORDINATOR OR RESEARCH ADMINISTRATIVE CONTACT FOR THIS APPLICATION (if not the PI):

☐ Not Applicable

Name: Bruce Urich			
Telephone: (416) 978-5386	Pager: N/A	FAX: (416) 978-2608	Email: bruce.urch@utoronto.ca
Mailing Address: 223 College St., Toronto, ON M5T 1R4			



**4. INVESTIGATORS:****A. PRINCIPAL INVESTIGATOR**

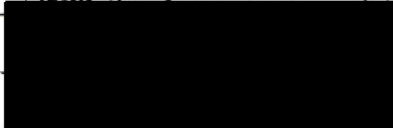
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\_\_\_\_\_  
Signature of Principal Investigator\_\_\_\_\_  
DateB. CO-INVESTIGATOR(S):

Name	Dept/Div/Program	Signature (if required at this institution—see instructions)
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C. STUDY COORDINATOR OR RESEARCH ADMINISTRATIVE CONTACT FOR THIS APPLICATION (if not the PI):☐ Not Applicable

Name: Bruce Urch			
Telephone: (416) 978-5886	Pager: N/A	FAX: (416) 978-2608	Email: bruce.urch@utoronto.ca
Mailing Address: 223 College St., Toronto, ON M5T 1R4			

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**C. Study Coordinator or Research Administrative Contact for this Application (if not the PI):**  
Not Applicable

Name: Bruce Urch			
Telephone: (416) 978-5886	Pager: N/A	FAX: (416) 978-2608	Email: bruce.urch@utoronto.ca
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Mailing Address: 223 College St., Toronto, ON M5T 1R4			

Please indicate to whom correspondence should be sent: ☐ PI ☒ Administrative Contact

**D. ON STAFF INVESTIGATOR (for studies initiated outside of this institution):**

☒ Not Applicable

Name:			
Telephone:	Pager:	FAX:	Email:
Dept/Division:		Program:	
Mailing Address:			


**5. FACULTY SUPERVISOR (for student/fellow/resident research studies):**

☐ Not Applicable

Name: Frances S. Silverman			
Telephone: (416) 978-5883	Pager: N/A	FAX: (416) 978-2608	Email: frances.silverman@utoronto.ca
Dept/Division: Medicine		Program: Gage Occupational and Environmental Health	
Mailing Address: 223 College St. Toronto, ON M5T 1R4			
Signature:			Date:

**6. DIVISION/DEPARTMENT/PROGRAM APPROVAL**

I am aware of this proposal and support its submission for ethics review. I consider it to be feasible and appropriate.

Linda Howess      OCC HEALTH            13 June 2005  
 Name (Print)      Div./Dept./Program (Print)      Signature      Date

**7. INVESTIGATOR CLASSIFICATION**

Staff Research: ☒ YES ☐ NO  
 Student Research: ☐ Post-Doctoral ☐ PhD ☐ Master's ☐ Undergraduate ☐  
 Resident/Fellow  
 Other (Please specify):

**8. SCIENTIFIC/SCHOLARLY REVIEW**

Has this proposal received prior scientific peer review? ☒ YES ☐ NO  
 If YES, indicate where and attach any relevant reviewer comments. Review committee of NCER (US- Environmental Protection Agency, National Center for Environmental Research)  
 If NO, please refer to institutional instruction page regarding possible review requirements.

**9. MATERIAL TRANSFER AGREEMENT**

Is there a material transfer agreement (MTA) involving human material for this study? ☐ YES ☒ NO  
 If YES, please attach a copy.